

REMARKS

Claims 1-41 are pending in the application. Claims 3, 5-14, 20 and 23-41 are withdrawn from consideration. Claims 1, 17, 19 and 21 have been amended to better clarify what Applicants regard as the invention. No new matter has been added by way of this amendment. Thus, as a result of the foregoing amendment, claims 1, 2, 4, 15-19, 21 and 22 remain under consideration.

The amended claims are shown above without markings. Attached hereto is a version with markings to show the changes made, captioned "Version with markings to show changes made."

The Examiner has objected to the disclosure in the specification because the application claims priority to 09/545,958 rather than 09/565,958. Applicants have amended the specification to correct the typographical error where necessary. The correction has been made and withdrawal of the objection is thus respectfully requested.

The Examiner alleges that the Declaration is defective for not claiming priority to applications 09/565,958 and 09/251, 896. Applicants herein submit a substitute declaration to note priority to both non-provisional applications, U.S. Serial Nos. 09/565,958 and 09/251,896, as well as to the earlier filed U.S. provisional applications, U.S. Serial Nos. 60/075,356, 60/077,095 and 60/101,749. Withdrawal of the objection is thus respectfully requested.

Claims 1, 2, 4, 16-19, 21 and 22 are rejected under 35 U.S.C. §112, second paragraph for being indefinite. Applicants respectfully traverse the Examiner's rejection, and have also amended the claims to better clarify what Applicants regard as the invention. Support for the amendments can be found on page 18, lines 12-13 and lines 17-23, continuing on to page 19, lines 1-7 and lines 13-16. Thus, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1, 4, 15, 16, 17, 19, 21 and 22 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Rovere et al in view of Migita et al and Banchereau and Guibinga et al.. Claims 1, 4, 15-19, 21 and 22 have also been rejected under 35 U.S.C. §103(a) as being unpatentable over Rovere and Migita et al and Banchereau and Guibinga et al further in view of Li et al and Sehgal. Applicants have amended the specification on page 1, lines 7-9

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under Cross-Reference to Related Applications to include reference to the earlier filed U.S. Provisional Applications. Applicants assert that the rejection under 35 U.S.C. §103(a) is mooted since the filing date of the earliest filed provisional application to which the present application claims priority precedes the earliest publication date of the cited references. Thus, Applicants respectfully request withdrawal of this rejection.

***Objections Based on Informalities***

The Examiner has objected to the disclosure because the application claims priority to 09/545,958 rather than 09/565,958. Applicants have amended the specification as suggested by the Examiner so that priority is now claimed to U.S. Serial No. 09/565,958. Withdrawal of the objection is respectfully requested.

***Defective Declaration***

The Examiner alleges that the Declaration is defective for not claiming priority to applications 09/565,958 and 09/251,896. Applicants herein submit an executed substitute declaration to replace the defective declaration and note priority to both non-provisional applications, U.S. Serial Nos. 09/565,958 and 09/251,896, as well as to the earlier filed U.S. provisional applications, U.S. Serial Nos. 60/075,356, 60/077,095 and 60/101,749. Withdrawal of the objection is respectfully requested.

***Claim Rejections under 35 U.S.C. §112***

Claims 1, 2, 4, 16-19, 21 and 22 have been rejected under 35 U.S.C. 112, second paragraph for being vague and indefinite.

Applicants respectfully traverse Examiner's rejection and have amended the claims to better clarify what Applicants regard as the invention.

In particular, the recitation of "pre-selected antigen" has been amended to read "an antigen". Support for this can be found on page 18, lines 20-21, wherein Applicants note that the antigen referred to in the claims as amended denotes any antigen to which tolerance is desired.

Furthermore, the recitation of "a cellular portion of step c" in claim 1 has been amended to read "the dendritic cells of step c)" to clarify that what is meant is the dendritic cells after exposure to apoptotic cells, without the supernatant or culture medium. Support for the amendment can be found on page 18, lines 12-13, and on page 19, lines 13-16.

The examiner has also rejected claim 17 for being vague and indefinite by reference to FK-506 as being a trade name. Applicants respectfully traverse the rejection and have amended the claim to recite "tacrolimus" as the more commonly used name for FK-506. Furthermore, Applicants respectfully point out that the tradename for FK-506/tacrolimus is "Prograf®". Prograf® is manufactured by Fujisawa for prophylaxis of organ rejection in patients receiving kidney or liver transplants. Support for this is provided in the attached document entitled "Search Results for FK506".

#### ***Claim Rejections under 35 U.S.C. §103(a)***

Claims 1, 4, 15, 16, 17, 19, 21 and 22 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Rovere et al. in view of Migita et al. and Banchereau and Guibinga et al.. Claims 1, 4, 15-19, 21 and 22 have also been rejected under 35 U.S.C. §103(a) as being unpatentable over Rovere et al. and Migita et al. and Banchereau and Guibinga et al. further in view of Li et al. and Sehgal. Withdrawal of these rejections is believed to be warranted for the following reasons.

Applicants have amended the specification on page 1, lines 7-9 under Cross-Reference to Related Applications to include reference to the earlier filed U.S. Provisional Applications. The Examiner will appreciate that the rejection under 35 U.S.C. §103(a) is now properly mooted since the filing date of the earliest filed provisional application to which the present application claims priority precedes the earliest publication date of the cited references. Thus, Applicants respectfully request withdrawal of this rejection.

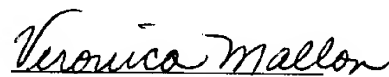
#### ***Fees***

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or to credit any overpayments.

***Conclusion***

Applicants believe that the foregoing amendments to the claims place the application in condition for allowance. Withdrawal of the rejections and objections is respectfully requested. If a discussion with the undersigned will be of assistance in resolving any remaining issues, the Examiner is invited to telephone the undersigned at (201) 487-5800, ext. 118, to effect a resolution.

Respectfully submitted,

  
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Enclosures: Version with Markings to Show Changes Made  
Substitute Declaration (executed)  
Search for "fk506"



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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IN THE SPECIFICATION:

The following amended paragraph shall replace the original paragraph on page 1, lines 7 through 9:

This application is a continuation-in-part of U.S. Serial No. 09/5[4]65,958, filed May 5, 2000, and a continuation-in-part of U.S. Serial No. 09/251,896, filed February 19, 1999, which claims priority to U.S. Provisional applications Serial No. 60/075,356, filed February 20, 1998; and Serial No. 60/077,095, filed March 6, 1998; and Serial No. 60/101,749, filed September 24, 1998, [both] all of which are incorporated herein by reference in their entireties.

IN THE CLAIMS:

The following amended claims 1, 17, 19 and 21 shall replace the pending claims having the same claim numbers:

1. (Amended) A method for inducing tolerance in a mammal to [a pre-selected] an antigen comprising the steps of
  - a. isolating peripheral blood mononuclear cells (PBMC) from a whole blood sample from said mammal;
  - b. isolating dendritic cells from said PBMC;
  - c. exposing said dendritic cells *ex vivo* to apoptotic cells expressing said [pre-selected] antigen in the presence of at least one dendritic cell maturation stimulatory molecule and in the absence of effective CD4<sup>+</sup> T cell help;
  - d. introducing [a] the [cellular portion] dendritic cells of step c) into said mammal;wherein said dendritic cells induce apoptosis of antigen-specific CD8<sup>+</sup> T cells in said mammal resulting in tolerance to said antigen.

17. (Amended) The method of claim 16 wherein said FKBP antagonist is [FK-506] tacrolimus.

19. (Amended) The method of claim 1 wherein said [pre-selected] antigen is a tumor antigen, a viral antigen, a self-antigen or a transplant antigen.

21. (Amended) The method of claim 1 wherein after a period of time following step c), [a cellular portion] the dendritic cells [is] are infused into the mammal.